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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,121	02/28/2006	Ilya Chumakov	ARS-125	7412

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SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
PO BOX 142950
GAINESVILLE, FL 32614-2950

EXAMINER	
KOSSON, ROSANNE	
ART UNIT	PAPER NUMBER
1652	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/570,121	CHUMAKOV ET AL.	
	Examiner	Art Unit	
	Rosanne Kosson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *43-65* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 44-46, drawn to a polynucleotide comprising nucleotides 1018-1046 and 1676-1718 of SEQ ID NO:1, and to a vector and host cell comprising the polynucleotide, and to a method of making the encoded polypeptide that is the step of culturing the host cell.

Group 2, claim(s) 44-46, drawn to a polynucleotide comprising SEQ ID NO:2, and to a vector and host cell comprising the polynucleotide, and to a method of making the encoded polypeptide that is the step of culturing the host cell.

Group 3, claim(s) 44-46, drawn to a polynucleotide comprising SEQ ID NO:52, and to a vector and host cell comprising the polynucleotide, and to a method of making the encoded polypeptide that is the step of culturing the host cell.

Group 4, claim(s) 44-46, drawn to a polynucleotide comprising SEQ ID NO:54, and to a vector and host cell comprising the polynucleotide, and to a method of making the encoded polypeptide that is the step of culturing the host cell.

Group 5, claim(s) 44-46, drawn to a polynucleotide comprising SEQ ID NO:55, and to a vector and host cell comprising the polynucleotide, and to a method of making the encoded polypeptide that is the step of culturing the host cell.

Groups 6-101, claim(s) 44-46, drawn to one mutant polynucleotide that is a mutant of SEQ ID NO:2 comprising one mutation listed in claim 44(c)(V), and to a vector and host cell comprising the polynucleotide, and to a method of making the encoded polypeptide that is the step of culturing the host cell. Group 6 comprises marker (mutation) no. 1; Group 7 comprises marker (mutation) no. 2; Group 8 comprises marker (mutation) no. 3, etc.

Groups 102-197, claim(s) 44-46, drawn to one mutant polynucleotide that is a mutant of SEQ ID NO:52 comprising one mutation listed in claim 44(c)(V), and to a vector and host cell comprising the polynucleotide, and to a method of making the encoded polypeptide that is the step of culturing the host cell. Group 102 comprises marker (mutation) no. 1; Group 103 comprises marker (mutation) no. 2; Group 104 comprises marker (mutation) no. 3, etc.

Groups 198-293, claim(s) 44-46, drawn to one mutant polynucleotide that is a mutant of SEQ ID NO:54 comprising one mutation listed in claim 44(c)(V), and to a vector and host cell comprising the polynucleotide, and to a method of making the encoded polypeptide that is the step of culturing the host cell. Group 198 comprises marker (mutation) no. 1; Group 199 comprises marker (mutation) no. 2; Group 200 comprises marker (mutation) no. 3, etc.

Groups 294-389, claim(s) 44-46, drawn to one mutant polynucleotide that is a mutant of SEQ ID NO:54 comprising one mutation listed in claim 44(c)(V), and to a vector and host cell comprising the polynucleotide, and to a method of making the encoded polypeptide that is the step of culturing the host cell. Group 294 comprises marker (mutation) no. 1; Group 295 comprises marker (mutation) no. 2; Group 296 comprises marker (mutation) no. 3, etc.

Group 390, claim(s) 44, drawn to a polypeptide encoded by a polynucleotide comprising nucleotides 1018-1046 and 1676-1718 of SEQ ID NO:1.

Groups 391-394, claim(s) 44, drawn to one polypeptide encoded by a polynucleotide comprising one of SEQ ID NOS: 2, 52, 54 or 55. Group 391 is encoded by SEQ ID NO:2; Group 392 is encoded by SEQ ID NO:52, etc.

Groups 395-778, claim(s) 44, drawn to one polypeptide encoded by one mutant polynucleotide that is a mutant of SEQ ID NO:2 or SEQ ID NO:52 or SEQ ID NO:54 or SEQ ID NO:55 that comprises one mutation listed in claim 44(c)(V). Group 395 is encoded by a mutant of SEQ ID NO:2 that comprises marker (mutation) no. 1; Group 491 is encoded by a mutant of SEQ ID NO:52 that comprises marker (mutation) no. 1; Group 587 is encoded by a mutant of SEQ ID NO:54 that comprises marker (mutation) no. 1, etc. If two or more of the claimed polynucleotides encode the same protein, Applicants are requested to identify the polynucleotides that have silent mutations.

Group 779, claim(s) 44, drawn to a polypeptide comprising SEQ ID NO:3 or a fragment of SEQ ID NO:3 having at least 470 contiguous amino acids or at least 15 contiguous amino acids within the range of amino acids 467-482.

Groups 780-875, claim(s) 44, drawn to a polypeptide comprising a mutant of SEQ ID NO:3 or a fragment of SEQ ID NO:3 having at least 470 contiguous amino acids or at least 15 contiguous amino acids within the range of amino acids 467-482, wherein the mutation is encoded by codon having one of the markers (mutations) listed in claim 44(c)(V). Group 780 is encoded by a mutant of SEQ ID NO:3 that comprises marker (mutation) no. 1; Group 781 is encoded by a mutant of SEQ ID NO:3 that comprises marker (mutation) no. 2, etc. If two or more of the claimed polynucleotides encode the same protein, Applicants are requested to identify the polynucleotides that have silent mutations.

Group 876, claim(s) 44, drawn to a polypeptide comprising SEQ ID NO:53 or a fragment of SEQ ID NO:53 having at least 470 contiguous amino acids or at least 15 contiguous amino acids within the range of amino acids 467-485.

Groups 877-972, claim(s) 44, drawn to a polypeptide comprising a mutant of SEQ ID NO:53 or a fragment of SEQ ID NO:56 having at least 470 contiguous amino acids or at least 15 contiguous amino acids within the range of amino acids 467-485, wherein the mutation is encoded by

codon having one of the markers (mutations) listed in claim 44(c)(V). Group 877 is encoded by a mutant of SEQ ID NO:56 that comprises marker (mutation) no. 1; Group 878 is encoded by a mutant of SEQ ID NO:56 that comprises marker (mutation) no. 2, etc. If two or more of the claimed polynucleotides encode the same protein, Applicants are requested to identify the polynucleotides that have silent mutations.

Group 973, claim(s) 44, drawn to a polypeptide comprising SEQ ID NO:56 or a fragment of SEQ ID NO:56 having at least 270 contiguous amino acids or at least 15 contiguous amino acids including amino acids 266 and 267.

Groups 974-1069, claim(s) 44, drawn to a polypeptide comprising a mutant of SEQ ID NO:56 or a fragment of SEQ ID NO:56 having at least 270 contiguous amino acids or at least 15 contiguous amino acids including amino acids 266 and 267, wherein the mutation is encoded by codon having one of the markers (mutations) listed in claim 44(c)(V). Group 974 is encoded by a mutant of SEQ ID NO:56 that comprises marker (mutation) no. 1; Group 975 is encoded by a mutant of SEQ ID NO:56 that comprises marker (mutation) no. 2, etc. If two or more of the claimed polynucleotides encode the same protein, Applicants are requested to identify the polynucleotides that have silent mutations.

Groups 1070-1360, claim(s) 44, drawn to one antibody that binds to one polypeptide claimed in one of Groups 779-1069. The antibody of Group 1070 binds to the polypeptide of Group 779; the antibody of Group 1071 binds to the polypeptide of Group 780, etc.

Groups 1361-1744, claim(s) 46-48, drawn to a method of purifying one polypeptide of one of Groups 390-778 and a method of formulating the purified polypeptide as a pharmaceutical composition. Group 1361 is a method of purifying the polypeptide of Group 390; Group 1362 is method of purifying the polypeptide of Group 391, etc.

Groups 1745-2035, claim(s) 49-52, drawn to a method of screening for ligands to or modulators of one polypeptide of one of Groups 779-1069. Group 1745 is a screening assay method using the polypeptide of Group 779; Group 1746 is a screening assay method of using the polypeptide of Group 780, etc.

Groups 2036-2326, claim(s) 53-56, drawn to a method of treating psoriasis, comprising administering to an animal a modulator of one polypeptide of one of Groups 779-1069. Group 2036 is a method using the polypeptide of Group 779; Group 2037 is a method of using the polypeptide of Group 780, etc.

Group 2327-2415, claim(s) 57-65, drawn to a method of genotyping an individual and determining whether or not the individual is at risk for psoriasis, comprising detecting one of the markers of claim 44(c)(V) with the exclusion of markers 3, 5, 8, 9, 11, 20 and 36. Group 2327 is a method of genotyping for marker no. 1; Group 2327 is a method of genotyping for marker no. 2; Group 2328 is a method of genotyping for marker no. 4, etc.

The inventions listed as Groups 1-2415 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The requirement of unity of invention is not fulfilled because there is no technical relationship among these inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Therefore, a technical relationship is lacking among the claimed inventions involving one or more special technical features. The specification makes it abundantly clear that the different proteins and polynucleotides recited in the claims each have a different structure and a different sequence. Some of the claimed polypeptides comprise only 15 amino acids of one of the polypeptides in the sequence listing. The different proteins and polynucleotides are those that are related to SEQ ID NO:1, as they are fragments and mutants of SEQ NO:1. Thus, the technical feature that links the 2415 groups of inventions is SEQ ID NO:1.

The inventions of Groups 1-2415 do not share the common special technical feature of SEQ ID NO:1, because Guillaudeux et al. ("The complete genomic sequence of 424,015 bp at the centromeric end of the HLA class I region: gene content and polymorphism," PNAS 95(16):9494-9499, 1998) disclose the polynucleotide of SEQ ID NO:1, the human 6p21 gene locus. See the enclosed alignment of SEQ ID NO:1 with the polynucleotide of Guillaudeux et al., Result 2 from a search in the GenEmbl nucleotide database, showing 100% sequence identity between the two sequences.

Thus, the technical feature of SEQ ID NO:1 does not define the invention over the prior art. Because the common technical feature is not novel (special) with respect to the cited reference, it is clear that the claims of Groups 1-2415 lack a single common technical feature that defines them over the prior art.

Further, an international application containing claims to different categories of inventions will be considered to have unity of invention if the claims are drawn only to one of certain combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or
(2) A product and process of use of said product; or
(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
(4) A process and an apparatus or means specifically designed for carrying out the said process; or
(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process (see 37 CFR 1.475(b)-(d)). In the instant case, the claims are drawn to multiple products and multiple processes, only a particular combination of which including Group 1 may be considered for unity of invention, i.e., Group 1 and Group 1361, (the first named product and the first named process of using the product). Other groups are drawn to additional products and processes, and other combinations do not comply with the aforementioned Rules. But, because a corresponding special technical feature is not present, Groups 1 and 1361 cannot be considered to have unity of invention.

Regarding the different claimed sequences, Applicants must choose **ONE** polypeptide or one polynucleotide from among those claimed as indicated in the different groups above. Each

sequence is a distinct invention requiring separate searches. THESE ARE NOT SPECIES. Each sequence is a chemically, structurally and functionally distinct molecule. Therefore, the each of the polynucleotides and each of the polypeptides is patentably distinct.

Moreover, each sequence requires a separate set of searches. Applicants should note that searching each sequence imposes a serious search burden. Currently, there are approximately eight different databases that accompany the results of a search for one discrete amino acid or nucleic acid sequence, and each result set from a particular database must be carefully considered. Each set of prior art has its own considerations with respect to anticipation and obviousness. Hence, the search for even two different polypeptides or polynucleotides in the databases, in addition to searching the organic molecule databases, would require extensive searching and review. Each mutant sequence requires a separate and distinct search that is not required for any other mutant sequence. Therefore, these inventions are patentably distinct.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: a natural ligand, or a small molecule, or an aptamer, or an antisense mRNA, or a small interfering RNA or an antibody (claim 50).

If Applicants elect one of Groups 1745-2035, Applicants must elect one of the modulators listed in claim 50.

Applicants are required, in reply to this action, to elect a single species of modulator to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is

considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 49.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons. Each modulator has a different structure, a different function and a different effect and requires a unique search. For example, an siRNA is a very different molecule than an antibody. Because the claimed species are not art-recognized equivalents, a holding of lack of unity of invention is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicants are advised that the reply to this requirement to be complete must

include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is (571)272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth Slobodyansky/

Rosanne Kosson
Examiner, Art Unit 1652

Elizabeth Slobodyansky, PhD
Primary Examiner, Art Unit 1652

rk/2008-02-22